

NOT YET SCHEDULED FOR ORAL ARGUMENT

No. 24-5294

UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY,
CENTER FOR ENVIRONMENTAL HEALTH,
Plaintiffs-Appellants,

v.

LEE M. ZELDIN, in his official capacity as Administrator of the
U.S. Environmental Protection Agency,
ENVIRONMENTAL PROTECTION AGENCY,
Defendants-Appellees,

INHANCE TECHNOLOGIES, LLC,
Intervenor-Appellee.

Appeal from the United States District Court for the District of Columbia
No. 1:24-cv-02194 (Hon. James E. Boasberg)

APPELLANTS' REPLY BRIEF

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GLOSSARY

CEH	Center for Environmental Health
PEER	Public Employees for Environmental Responsibility
EPA	Environmental Protection Agency
TSCA	Toxic Substances Control Act
PFAS	Per- and poly-fluoroalkyl substances
PFOA	Perfluorooctanoic acid

INTRODUCTION

Plaintiffs in this case seek to enforce the mandatory duty of the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) to address unusually serious threats to health from highly toxic Per- and poly-fluoroalkyl substances (PFAS). The Agency first recognized these threats nearly five years ago but millions of Americans who use fluorinated plastic containers remain at significant risk. EPA does not dispute the magnitude of the threat or deny its obligation under section 4(f) of TSCA to “prevent or reduce” the risk it presents by the 180-day statutory deadline. Its sole defense for not affording timely protection is that, by seeking public comment on limited issues that might arise in a future rulemaking, it did all that section 4(f) required.

In section 4(f), Congress went to great lengths to create an enforceable duty for addressing severe and immediate threats from chemicals and set a high bar for the health protection EPA must provide to discharge this responsibility. It also imposed a mandatory duty on EPA under section 7(a)(2) to address imminent hazards. Plainly, Congress did not envision that EPA could do next to nothing and then walk away from these obligations. Yet EPA’s interpretation of TSCA would enable the Agency to take token actions that fail to address urgent risks and claim it has done its job. The language and intent of TSCA demand that EPA do more. The Court should assure that EPA performs its duties.

BACKGROUND

EPA began investigating the fluorination process of intervenor Inhance Technologies LLC (Inhance) in 2020 after its testing demonstrated the presence of harmful PFAS in a widely used mosquito control pesticide distributed in fluorinated packaging. Pl. Br. 10-11. There is no dispute that, by the end of 2022, EPA knew that Inhance fluorinated approximately 200 million plastic containers a year; that Perfluorooctanoic acid (PFOA) and several other PFAS were formed during fluorination and consistently present in plastic containers and their contents; that millions of consumers and workers were exposed to PFAS from the use of fluorinated containers; and that these PFAS were released into the environment at all stages of the fluorinated container life-cycle. Id. 34-39. There is also no dispute that, by early 2023, EPA had determined that PFOA, perhaps the most harmful member of the PFAS class, is “likely to cause cancer . . . and there is no dose below which ... [it] is considered safe.” Id. 11-15.

EPA’s lengthy investigation culminated on December 1, 2023 with a comprehensive risk assessment determining that formation of PFOA and two other PFAS during fluorination “presents an unreasonable risk of injury to health or the environment” under TSCA section 5(a)(3). JA132-136. Simultaneously, EPA issued an order under section 5(f) banning Inhance from forming these PFAS during fluorination and prohibiting the distribution and use of fluorinated

containers contaminated by PFAS. JA128-139. However, the order was vacated by the Fifth Circuit’s March 2, 2024 decision holding that EPA exceeded its authority under TSCA section 5. *Inhance Technologies, LLC v. EPA*, 96 F.4th 888 (5th Cir. 2024). While blocking action under section 5, the Court emphasized that EPA had ample authority under section 6 of TSCA to regulate fluorination and raised no concerns about EPA’s determination of unreasonable risk and supporting risk assessment. *Id.* at 895.

On April 11, 2024, plaintiffs filed a petition under TSCA section 21 maintaining that “EPA’s unreasonable risk determination under TSCA Section 5 obligates [it] to . . . initiate a rulemaking under TSCA Section 6(a) to eliminate the unreasonable risks caused by the production and processing of [PFAS] during” fluorination. JA47-180. While the petition was pending, on May 17, 2024, plaintiffs submitted a notice of intent to sue EPA under Section 20(b)(2) to compel it to comply with its obligations under TSCA sections 4(f) and 7(a)(2). JA17-18. The notice emphasized that the evidence warranting rulemaking under section 6(a) also triggered expedited action to prevent or reduce the risk under sections 4(f) and 7 but EPA had not taken these required actions.

In a July 10, 2024 letter, the Agency “granted” the petition. JA 38-41. However, the petition response did not address plaintiffs’ pre-suit notice or acknowledge its mandatory duties to address fluorination risks under sections 4(f)

and 7(a)(2). On July 25, 2024, plaintiffs therefore filed a citizens’ suit in the District Court to compel EPA to comply with these duties. A month later, on September 24, 2024, EPA issued a short Federal Register notice seeking public comment on a few narrow issues, including the “uses of fluorinated containers” and “alternatives to the fluorination process.” JA42-46. EPA had earlier received extensive information on these subjects from Inhance (Pl. Br. 43 n.12) but maintained that it needed further input to develop certain economic analyses required for a future section 6 rulemaking. However, the notice took no concrete action to eliminate the unreasonable risks of fluorinated containers and was again silent on EPA’ mandatory duties under sections 4(f) and 7(a)(2). Not until its motion to dismiss in the District Court (Dkt. No. 14) did EPA argue that its request for comment discharged these obligations.

In the year since the request for comment, EPA has taken no further action on fluorinated containers under TSCA.

I. EPA’s September 24, 2024 Request for Comment Did Not Discharge Its Mandatory Duty under TSCA Section 4(f)

A. The District Court Recognized that EPA Was in Violation of Section 4(f) but Allowed Minimal Steps to Come into Compliance

The District Court recognized that, “once the agency was in possession of information showing that PFOA ‘presents a significant risk of serious or widespread harm to human beings,’ it faced a nondiscretionary duty to ‘initiate applicable action [under TSCA section 4(f)] . . . within 180 days.’” JA200. The

Court further agreed that, “[t]aking Plaintiffs’ allegations as true, EPA’s [section 4(f)] duty] arose by March 29, 2023 — which means that it was tardy in its initial order against Inhance (in December 2023) and similarly dragged its feet after the Fifth Circuit vacated its Order” on March 2, 2024. *Id.*

The sole basis for the District Court’s order of dismissal was that EPA’s September 24, 2024 request for comment satisfied its duty under section 4(f) because it was “explicitly designed to ‘inform the Agency’s regulation of’ the relevant PFAS” and therefore initiated action under section 6. JA201. This conclusion was incorrect. Section 4(f) requires EPA to do far more than seek information on a limited set of issues that have some connection to future section 6 regulation. It directs that the Agency “shall . . . initiate applicable action under section [6] to prevent or reduce [a significant risk of serious or widespread harm] to a sufficient extent” within 180 days. EPA’s request for comment did not satisfy this duty.

To begin with, collecting information from the public in advance of a rulemaking is not an “applicable action” under section 6. The steps in the rulemaking process are detailed in sections 6(a) and 6(c). The only reference to public comment is in paragraph 6(c)(3)(B), which allows “interested persons to submit written data, views, and arguments” on a proposed rule but is silent on the need for comment before the commencement of rulemaking. Thus, obtaining

public input before publishing a proposal is not a required step in section 6 rulemaking and could not “initiate [] action” because it was outside the prescribed rulemaking process.

Second, the information request fell far short of section 4(f)’s requirement to initiate action “to prevent or reduce to a sufficient extent the [significant risk of serious or widespread harm]” from fluorination. TSCA prescribes in great detail the rulemaking process that EPA must follow to regulate unsafe chemicals under section 6(a). But EPA took none of these required steps.

For example, where (as here) EPA has determined that a substance presents an unreasonable risk to health or the environment, section 6(a) directs that it “*shall* by rule . . . apply one or more of” seven enumerated requirements (emphasis added). In choosing among these options, EPA must regulate a substance “to the extent necessary so that [it] no longer presents [an unreasonable] risk.” However, EPA’s Federal Register notice failed to identify which of these authorized regulatory restrictions it planned to apply to fluorination and to take concrete steps to propose a rule imposing these restrictions. Thus, EPA ignored its basic statutory responsibility – to initiate action that would “prevent or reduce” these risks “to a sufficient extent.”

B. The “First Step” in Section 6(a) Rulemaking is a Proposed Rule, Not Economic Analyses to Support a Future Proposal

EPA’s brief argues that the economic and alternatives analyses it must develop under sections 6(c)(2)(A) and (C) are the “‘first steps’ of the rule-making process” and that it “may need to collect and evaluate information to prepare those analyses.” It claims that these “preliminary steps . . . must be completed [before] . . . EPA may proceed to propose a rule under section 6(a).” EPA Br. 24.

This is not how Congress structured TSCA’s process and timeline for section 6(a) rulemaking. Under the statute, the “first step” in this rulemaking is a proposed rule. Section 6(c)(1)(A) directs that, after EPA “determines that a chemical substance presents an unreasonable risk of injury,” it “*shall* propose in the Federal Register a rule under subsection (a) . . . not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published” (emphasis added).¹ Per section 6(a), this proposal “shall” include specific requirements for eliminating the unreasonable risk. Under TSCA section 6(c)(3), EPA’s proposal must also “stat[e] with particularity the reason for the proposed rule” and “make and publish with the rule the determination [of unreasonable risk].”

¹ Paragraph (c)(1)(B) requires that EPA “*shall* publish . . . a final rule” not later than 2 years after publication of the risk evaluation (emphasis added). Under paragraph (c)(1)(C), these deadlines may be postponed “for not more than 2 years.”

Nowhere does section 6(c) provide that the section 6(c)(2)(A) and (C) economic and alternatives analyses must *precede* a proposed rule.² In fact, this would be contrary to their role in the rulemaking process. Since they must provide data on the economic impacts of the requirements in the proposal and other options considered, EPA cannot conduct the analyses before defining the proposed rule's requirements.³ Therefore, paragraph (c)(2)(A) states that EPA "shall consider and publish" the analyses "in proposing and promulgating a rule under subsection (a)"—not in advance of formal rulemaking.

In short, EPA's reading of section 6 would invert the rulemaking framework designed by Congress, treating an early informal request for comment that TSCA does *not* prescribe as the initiating action in section 6 rulemaking while ignoring the law's explicit designation of a proposed rule as the first step in the rulemaking process.⁴

² The declaration submitted to the lower court by Dr. Bennett demonstrated that the notice was superfluous because EPA's investigation of Inhance provided all the information needed for a section 6 rulemaking. JA192. Her recent review of the docket showed that only one user of fluorinated containers submitted any information responsive to EPA's questions.

<https://www.regulations.gov/comment/EPA-HQ-OPPT-2024-0131-0021>.

³ Paragraph (c)(2)(A) requires EPA to analyze "the reasonably ascertainable economic consequences of the . . . proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered."

⁴ EPA does not cite any prior section 6 rulemakings in which it sought public comment to inform its section 6(c)(2) regulatory analyses before issuing a proposed rule.

Inhance mistakenly asserts that EPA’s “cost-benefit” analyses must inform its decision to proceed with a proposed rule and therefore might result in a decision that no rule is needed. In. Br. 28. But Congress specifically amended TSCA in 2016 to reverse the Fifth Circuit’s 1991 ruling that section 6 rules must be based on cost-benefit balancing. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). Instead, as discussed above, the amended law provides that EPA *must* initiate a rulemaking upon making a determination of unreasonable risk and is then *required* to eliminate that risk, not to balance it against economic concerns. Section 6(c)(2)(B) confirms that EPA must only consider its economic analyses “to the extent practicable”—that is, without violating the statutory directive to identify and eliminate unreasonable risk without regard to economic factors.

Because publication of a proposed rule is the initiating action in the section 6 rulemaking process under TSCA, it was necessarily the step required to “initiate applicable action” under section 4(f). EPA wrongly asserts “it is unrealistic to think that Congress expected EPA to complete a typically years-long regulatory process in six to nine months” under section 4(f).⁵ EPA Br. 30. Once EPA has made a determination of unreasonable risk, Congress directed it to propose a rule in one year under section 6(c)(1)(A). This is only 90 days longer than the nine months

⁵ Section 4(f) allows EPA to extend the 180-day deadline by 90 days for “good cause.”

Congress prescribed for responding to section 4(f) information, which by its nature raises urgent public health concerns that demand an immediate response. It is thus not surprising that Congress would expect EPA to move quickly to rulemaking under section 6(a) within 270 days after triggering section 4(f).⁶

C. TSCA Does Not Compel a New Risk Evaluation on Fluorinated Containers

Appellees maintain that EPA’s 2023 risk assessment for fluorinated containers under section 5 did not fulfill the requirements for risk evaluations under section 6(b) and therefore could not trigger section 6(c)(2)’s one-year deadline for proposing a section 6(a) rule, which is predicated on a determination of unreasonable risk “in accordance with subsection (b)(4)(A).” EPA Br. 32.

The thrust of this argument is unclear. EPA does *not* maintain that, because of the alleged shortcomings of its section 5 risk assessment, it must now retrace its steps and conduct a new risk evaluation on fluorinated containers in compliance with section 6 and only then decide whether to undertake rulemaking under sections 6(a) and 4(f). Indeed, EPA’s brief concedes that it chose *not* to commence a new risk evaluation for fluorinated containers but instead “agreed to initiate an ‘appropriate proceeding’ to issue a rule under section 6(a) in response to Petitioner’s section 21

⁶ Here, EPA’s December 2023 risk assessment for fluorinated containers followed a three-year process to collect extensive information about their use, distribution and disposal. This effort provided a strong foundation for developing a proposed rule within the section 4(f) timeframe.

petition.” EPA Br. 23 n.5.

EPA’s petition response underscores its exclusive focus on rulemaking, not further risk evaluation. As the response noted, the petition asked EPA to “establish regulations pursuant to Section 6 . . . prohibiting” PFAS formation during fluorination. JA38. EPA granted this request, emphasizing that petitioners “established it is ‘necessary’ to initiate a proceeding for a rule under TSCA Section 6.”⁷ JA39. This conclusion presupposes an EPA finding that the fluorination process “presented an unreasonable risk of injury” that met the prerequisite for rulemaking under sections 6(a) and 6(c)(1)(A). In its comment request, EPA similarly stressed that it was seeking information to “inform regulations” under TSCA and would use the requested information “[i]n proposing and promulgating rules under TSCA section 6(a).” JA42-43. The comment request made no mention of a new risk evaluation.

In any case, it is not correct that EPA’s section 5 risk assessment for fluorinated containers did not comply with section 6(b)(4)(A). This provision requires EPA to:

determine whether [PFAS in these containers] present[] an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or

⁷ This finding tracks section 21(b)(1) which directs that petitions “shall set forth the facts which it is claimed establish that it is necessary to issue . . . a rule under section [6].”

susceptible subpopulation . . . under the conditions of use.

There is no doubt that EPA’s December 1, 2023 assessment contained these elements.⁸ While other paragraphs in section 6(b)(4) may prescribe additional requirements for risk evaluations, only paragraph (4)(A) is incorporated in sections 6(a) and 6(c)(1) and only its provisions must be satisfied to trigger EPA’s rulemaking obligations.

Inhance assumes that the only path to section 6 rulemaking under TSCA is through a lengthy process that starts with listing a substance as “high priority” under section 6(b)(1) and progresses through every risk evaluation step in section 6(b)(4)(A)-(H). In. Br. 30-31. But as EPA has recognized in responding to another section 21 petition, “a TSCA Section 6(a) rulemaking may occur absent a TSCA Section 6(b)(4) risk evaluation” and “the relevant standard is found in TSCA Section 6(a), which specifies the Administrator must formally ‘determine’ there is unreasonable risk” but need not conduct a full section 6(b) risk evaluation.⁹ *Food & Water Watch, Inc v. EPA*, 291 F. Supp. 3d 1033, 1046 (N.D. Cal. 2017) (“The

⁸ For example, the assessment made a determination of unreasonable risk for PFAS formed during fluorination without considering “costs or other non-risk factors,” addressed risks to “potentially exposed or susceptible subpopulations “and based its risk findings on detailed information about the “conditions of use” of fluorinated containers. JA66-126.

⁹ EPA Response to 6PPD Petition (Nov. 2, 2023) at 2.

https://www.epa.gov/system/files/documents/2023-11/pet-001845_tsca-21_petition_6ppd_decision_letter_esigned2023.11.2.pdf.

predicate for a rule is a finding of unreasonable risk . . . Section 21 [is a] pathway . . . that appears to be independent of the Section 6(b) risk evaluation process.”)

The full TSCA section 6(b) process requires at least 4.5 years (one year for prioritization per paragraph (b)(1)(C) and 3.5 years for a risk evaluation per paragraph (b)(4)(G)). To delay action on fluorinated containers for this extended period while EPA repeats a risk assessment it has already conducted would not only be wasteful but postpone urgently needed protections of public health that have already been substantially delayed. Fortunately, sections 6(a) and 6(c)(1) do not require this pointless exercise but require EPA to directly proceed with rulemaking following an unreasonable risk determination in accordance with section 6(b)(4)(A). EPA must follow this path here.

II. EPA Had a Non-discretionary Duty to File an Imminent Hazard Action Against Inhance

A. EPA’s Obligation to Address an Imminent Hazard Does Not Require a Section 6(a) Rule that is Not Immediately Effective

Inhance and EPA maintain that EPA has no mandatory duty enforceable under the citizen suit provision to file suit to remedy an “imminent hazard” unless the Agency has promulgated a rule under section 6(a) but not made it “immediately effective” under section 6(d)(3)(A). They claim this result is compelled by the “plain language” of section 7(a)(2) directing that EPA “shall commence” an imminent hazard action “[i]f the Administrator has not made a rule under section 2605(a) of this title immediately effective.” EPA Br. 38; In. Br. 34 -35. However, this is not the

natural reading of the statutory text. A more logical reading is that EPA's mandatory duty arises where EPA has failed to make "a rule . . . immediately effective" because no such rule has been promulgated. This construction of section 7(a)(2) both conforms to the statutory language and comports with TSCA's intent, structure and legislative history.

The standard for establishing an "imminent hazard" under TSCA is extremely high. Under section 7(f), a chemical must "present[] an imminent and unreasonable risk of serious or widespread injury to health or the environment" and this injury must be "likely" to occur "before a final rule under section 2605 of this title can protect against such risk." Thus, the risk of injury must not only be "serious or widespread" but immediate action must be warranted because the normal section 6 rulemaking process would be too slow to protect against imminent harm.

Yet under appellees' reading of section 7(a)(2), EPA's mandatory duty to file an imminent hazard suit would arise only where it has issued a section 6(a) rule but not taken the additional step of making it immediately effective. As discussed above, the normal section 6 process requires that a chemical first be designated as high priority, then undergo a full risk evaluation under section 6(b), and finally proceed to rulemaking under section 6(c). Since TSCA was amended in 2016, only five final section 6(a) rules have been promulgated and the process for each has taken nearly 8

years.¹⁰

If an imminent hazard could not be addressed for 8 years, citizens who are at immediate risk would lack a judicial remedy until long after serious harm had occurred. Even worse, where EPA has failed to use its rulemaking authority to address the threat and there is no section 6 rule, citizens would be without *any* judicial remedy at all.

TSCA section 20(b)(2), which requires would-be plaintiffs to notify EPA in advance of planned citizens' suits, emphasizes the importance Congress attached to timely enforcement of EPA's mandatory duty to address imminent hazards. The prescribed pre-suit notification period under this provision is 60 days for all suits except those seeking to compel EPA to file section 7(a)(2) actions, for which the notice period is only 10 days. Having gone to the trouble of expediting citizens' suits to compel EPA to address imminent hazards, it would be incongruous for Congress to then preclude these suits because EPA has either failed to initiate rulemaking or not yet completed it, foreclosing timely protection against imminent harm.

Struggling to justify this result, the District Court speculated that "[t]he regulatory paradigm . . . broadly leaves to EPA the decision of whether to file an

¹⁰ EPA's Website lists all chemicals progressing through the section 6 process and their current status, including whether final section 6(a) rules have promulgated. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>. The five chemicals with final rules were selected for risk evaluations in late 2016 and final rules were issued in 2024.

imminent-hazard suit,” except in the limited case where a section 6 rule is in effect but not immediately effective. JA204. But this “regulatory paradigm” has no support in TSCA’s text or legislative history. On the contrary, the Conference Report for the 1976 law emphasized that it imposed “a nondiscretionary duty upon the Administrator to insure that protection is provided against imminently hazardous substances.” H.R. Report No. 94-1679, 94th Cong., 2d Sess. 78 (1976).

B. TSCA Provides a Readily Ascertainable Deadline for Discharging EPA’s Mandatory Duty under Section 7

Appellees also claim that EPA has no mandatory duty because section 7(a)(2) does not set an express deadline for discharging it. EPA Br. 36. This argument ignores the overwhelming evidence that Congress intended to impose a mandatory duty on EPA and believed the enacted law accomplished that objective. Section 7(a)(2) is explicit that, in the absence of an immediately effective rule, “the Administrator *shall* commence . . . a civil action” to address an imminent hazard (emphasis added). “Ordinarily, legislation using ‘shall’ indicates a mandatory duty.” *Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016). As noted above, Congress’ intent is further reinforced by definitive legislative history recognizing EPA’s “non-discretionary duty” to protect against imminent hazards and its explicit authorization of citizens’ suits in section 20(b)(2) to compel EPA to address such hazards.

As this Court held in *Sierra Club v. Thomas*, 828 F.2d 783, 790 (D.C. Cir. 1987), “a nondiscretionary duty of timeliness may arise even if a deadline is not explicitly set forth in the statute, if it is readily-ascertainable by reference to some other fixed date or event.” This is the case here. The definition of “imminent hazard” in section 7(f) is a chemical that “presents an imminent and unreasonable risk of serious or widespread injury to health.” This language is virtually identical to the criteria for invoking section 4(f). Initiating action under section 7 is also among the three mechanisms Congress specified for responding to 4(f) information. The deadline for taking such action under section 4(f) is 180-270 days, which is an expeditious but realistic timeframe for filing suit to address serious risks of immediate concern. It is hardly a leap of faith to conclude that this same deadline should govern EPA’s separate mandatory duty to take action under section 7(a)(2) when faced with a risk of comparable urgency. Thus, the deadline is a “fixed date or event” whose application to EPA’s mandatory duty under section 7(a)(2) is “readily-ascertainable” from TSCA.

III. Plaintiffs’ Complaint and Declarations Provide Sufficient Evidence to Demonstrate Standing

A. Standing Should Be Considered, If at All, under the Relaxed Standard for the Pleading Stage, which Has Been Met Here

In the proceedings below, the Court granted EPA’s motion to dismiss, agreeing that its actions discharged its obligations under TSCA and the case was moot. JA193-206. Standing was not raised or decided. Thus, this Court could

simply decide plaintiffs’ appeal of the mootness dismissal, and if it reverses, leave standing to be adjudicated along with the merits by the district court on remand.

If standing is addressed by the Court, the controlling standard is that, “[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice [because] . . . we ‘presum[e] that general allegations embrace those specific facts that are necessary to support the claim.’” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561(1992) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990)). Thus, the question is whether plaintiffs’ Complaint “plausibly alleged standing,” not whether plaintiffs have “establish[ed] each element of standing by a preponderance of the evidence.” *AFGE v. OPM*, 928 F.3d 42, 54 (D.C. Cir. 2019). This is a “light burden of proof.” *Attias v. CareFirst, Inc.*, 865 F.3d 620, 626-27 (D.C. Cir. 2017).

The Complaint alleges that “CEH has approximately 50,000 supporters and over 100,000 social media followers across the United States;” that its Board members are “also supporters of CEH [and] actively engaged in helping to shape the direction of CEH’s work;” and that “[b]oard members, supporters and staff of CEH use a variety of products packaged in plastic containers that may be fluorinated.” JA13. The Complaint also alleges that PEER has “thousands of supporters and subscribers to its publications nationwide;” its “educational and advocacy work is instigated and informed by the input of its supporters;” its testing

in 2020 was “the first to bring to the attention of government agencies and the public the presence of PFAS in . . . containers fluorinated by Inhance;” and that its “Board members, supporters and staff . . . use a variety of products packaged in plastic containers that may be fluorinated by Inhance.” JA14. Under *Lujan*, these “general factual allegations” are plainly sufficient to establish standing on a motion to dismiss because they “embrace those specific facts that” may need to be established if standing is contested later in the case.

B. Plaintiffs Have Also Established Standing for the Merits Stage

Although the decision below was at the pleading stage, in an abundance of caution, plaintiffs complied with Circuit Rule 28(a)(7), requiring a standing demonstration by appellants seeking direct review of agency action. Plaintiffs’ opening brief thus argued the merits of their standing and was supplemented by two declarations from senior employees. As demonstrated below, these arguments and declarations amply demonstrate plaintiffs’ standing under the applicable caselaw.¹¹

¹¹ Inhance (but not EPA) insists that “[t]hese submissions are not properly before the Court” because they are being “present[ed] now for the first time on appeal.” In. Br. 23. However, such declarations were not germane at the pleading stage in the district court, and were submitted here in case this Court decided to fully address standing under Rule 28. This case is unlike *Summers v. Earth Island Inst.*, 555 U.S. 488 (2009), where standing had been litigated below and the respondents submitted additional standing affidavits to the district court after judgment.

1. Plaintiffs Satisfy the “Indicia of Membership” Test for Associational Standing

EPA, whose actions on fluorinated containers are the central focus of this appeal, “does not dispute that Plaintiffs have pleaded sufficient facts to show that [two of its senior] employees are ‘the functional equivalent’ of members” and therefore satisfy “the second and third prongs of the associational standing test.” EPA Br. 44. Inhance disagrees, claiming that PEER and CEH “are not membership organizations and therefore do not qualify for associational standing.” In. Br 16. Inhance is wrong.

In support of plaintiffs’ associational standing, EPA cites *Flyers Rts. Educ. Fund, Inc. v. United States Dep’t of Transp.*, 957 F.3d 1359, 1361–62 (D.C. Cir. 2020). That case upheld the standing of a non-membership organization “suing on behalf of . . . those individuals associated with the organization who are the ‘functional equivalent’ of members.” Associational standing existed because the organization and its supporters had “a sufficient amount of interaction to influence the organization’s activities” and because supporters “receive information from the organization,” have “direct input” into its priorities which “guides the organization’s activity” and provide “a majority of [its] funding.”

This is the case here. Plaintiffs’ interactions with their supporters are at least as extensive as those deemed sufficient by this Court. As Thomas Fox of CEH explains:

CEH has approximately 50,000 supporters across the United States who . . . help to drive our work by sharing their feedback and concerns. CEH’s supporters can influence CEH’s activities through participation in CEH’s Virtual Town Halls . . . Through our website and social media channels, we answer questions, offer resources, and provide ways to take action through petitions and campaigns. We also engage supporters as partners in our advocacy campaigns. . . . We also encourage our supporters to contact their elected representatives and companies regarding issues of concern to CEH and our supporters and provide educational resources to support their engagement . . . CEH relies significantly on contributions from its supporters, both big and small

Fox Decl. ¶¶8-10.

In *Air All. Houston v. U.S. Chem. & Safety Hazard Investigation Bd.*, 365 F. Supp. 3d 118, 128 (D.D.C. 2019), the district court upheld the associational standing of an environmental group that lacked traditional members who elect the Board of Directors because a “subset of members”—Board Members and the Executive Director—“exercise the governance function of the organization,” “members fund the organization through voluntary contributions,” and its “fortunes are tied to those of its constituency.” *Id.* at 129. The court relied on the Executive Director’s declaration documenting “injury to her health from exposure to chemical emissions” to meet the injury prong of standing. *Id.* at 130. Likewise here, PEER and CEH staff and board members exercise the governance functions of the organizations and contribute to their funding, and plaintiffs may therefore rely on injury to their staff to demonstrate associational standing. Fox Decl. ¶¶2, 8; Bennett Decl. ¶¶1, 6-9.

As this Court underscored in *Flyers Rts.*, other circuits have also found associational standing where an organization is “‘sufficiently identified with and subject to the influence of those it seeks to represent,’ even though it does not possess all three indicia of membership considered in *Hunt*.” 957 F.3d at 362 (citing cases). See also *Students for Fair Admissions, Inc. v. President & Fellows of Harv. Coll.*, 600 U.S. 181, 201 (2023) (“*SSFA*”) (finding associational standing even though the group’s members did not control or fund the organization, stating: “Where, as here, an organization has identified members and represents them in good faith, our cases do not require further scrutiny into how the organization operates”)¹²; *Inst. of Cetacean Research v. Sea Shepherd Conservation Soc’y*, 153 F. Supp. 3d 1291 (W.D. Wash. 2015) (employees and volunteers may count as members for purposes for associational standing).¹³ These decisions further support plaintiffs’ associational standing.

¹² Cases like *SSFA* and *Air All. Houston* use the term “members” somewhat loosely, to include supporters who do not have voting rights to elect the Board of Directors. PEER and CEH are not considered traditional membership organizations solely because their corporate structure does not include “members” who elect the Board of Directors. Their supporters, staff and board of directors are more like the “members” described in *SSFA* and *Air All. Houston* since they help exercise the governance functions of the organization, influence its actions, help fund it, and are represented by PEER and CEH in good faith.

¹³ In contrast, *Inhance* relies on clearly inapposite cases where the organization “has given us no insight into how it relates with its members,” *Viasat, Inc. v. Fed. Commc’ns Comm’n*, 47 F.4th 769, 781–82 (D.C. Cir. 2022), or putative members only “simply [] read a group’s publications.” *Sorenson Commc’ns v. Fed. Commc’ns Comm’n*, 897 F.3d 214, 225 (D.C. Cir. 2018).

2. Plaintiffs' Declarations Establish a Substantial Probability of Future Harm From Exposure to PFAS in Fluorinated Containers

As EPA admits, “[u]nwanted exposure to a hazardous substance is typically a cognizable injury.” EPA Br. 44. Its brief cites *Clean Wis. v. EPA*, 964 F.3d 1145, 1156 (D.C. Cir. 2020), holding that “[a]dverse health effects likewise constitute Article III injuries, even if a petitioner merely asserts realistic health concerns instead of providing medical evidence.” *Id.* This Court has “frequently upheld claims of standing based on allegations of a ‘substantial risk’ of future injury.” *Attias*, 865 F.3d at 626-27 (citing cases).

Yet appellees dispute standing because plaintiffs’ declarants “do not allege that any product they regularly use is likely to be packaged in a container fluorinated by Inhance,” EPA Br. 47, and have failed to “show a substantial probability that they will be exposed personally to PFAS from fluorinated containers.” *Id.* at 44. Even a cursory review of the declarations refutes these assertions.

These declarations show that Dr. Bennett and Mr. Fox have been (and continue to be) extensively exposed to products packaged in containers likely (if not certainly) fluorinated by Inhance. Mr. Fox routinely uses numerous outdoor products with plastic fuel tanks and several dog grooming cleaning products and shampoos. Fox Decl. ¶¶2-29. Dr. Bennett has ingested drinking water contaminated by PFAS

from a pesticide packaged in Inhance-fluorinated containers and used outdoor equipment with plastic fuel tanks and personal care products identified as fluorinated by Inhance. Bennett Decl. ¶¶17-19, 25-34.

Fluorination services for plastic fuel tanks for mowers, chain saws and other gasoline-fueled outdoor products are, by Inhance’s admission, “major markets” for its DuraBloc line of business. Fox Decl. ¶14. As Inhance itself observes, EPA has “issue[d] standards requiring the control of evaporative emissions by permeation from polyethylene fuel tanks” and fluorination may be the only currently available barrier technology for these plastic products. In. Br. 7. Since Inhance is the sole fluorination provider in the US, it is the source of all fluorinated gas tanks and cans used in outdoor products. Bennett Decl. ¶31.

Plaintiffs’ declarations also establish that their direct exposure to PFAS when using gasoline-fueled outdoor equipment creates serious health risks. According to Dr. Bennett’s Declaration, “Inhance’s own testing shows that levels of PFOA and other [PFAS] in fluorinated fuel tanks are significant, and substantial concentrations of LCPFACs leach into the fuel itself.” Id. ¶32. As she also explains, the presence of these PFAS in fuel tanks is a substantial source of PFAS exposure: “[u]sers of gasoline-powered outdoor products would be exposed to [PFAS] when they spill gasoline on their hands or wash tanks or gasoline cans, from gasoline vapors released during product operations or from emissions of engine exhaust.” Id. ¶33.

In 2023, Dr. Bennett’s blood was tested for the presence of PFAS and elevated levels were detected of PFOA and two other PFAS consistently found in fluorinated containers. According to Dr. Bennett, “their presence in my blood is evidence that I continue to be exposed to PFAS through these containers despite my efforts to avoid their use.” Id. ¶37.

Given EPA’s decades-long work on the health impacts of PFAS, it is no surprise that the Agency’s Brief does not dispute the serious harms to health that even minuscule levels of exposure can cause. EPA has repeatedly affirmed these risks since the early 2000s. Pl. Br. 12-14. Its 2023 risk assessment for fluorinated containers explained that PFAS produced by fluorination are persistent, bioaccumulative, and toxic and “[s]mall releases to the environment can have a significant long-term contribution to exposure and risk.” JA71, 95. EPA’s 5(f) order emphasized that, due to PFOA’s known carcinogenicity and other severe health effects, “there is currently no safe level of exposure.” JA168. It also noted that the “amount of these . . . PFAS in the environment will grow with each successive manufacture of fluorinated containers.” JA169. Accordingly, it concluded that “[a] prohibition on the manufacture of [PFOA and other PFAS during fluorination] is required because the risk cannot otherwise be adequately mitigated.” JA135.

In short, the health impacts of Mr. Fox’s and Dr. Bennett’s sustained PFAS exposure are not “hypothesized, non-imminent ‘injuries,’” *Center for L. and Educ. v.*

Dep't of Educ., 396 F.3d 1152, 1161 (D.C. Cir. 2005), but present “a substantial probability of harm.” *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2005). Indeed, in 2020, Dr. Bennett was diagnosed with a hemangioblastoma (a brain tumor) and had two brain surgeries. She is being monitored closely for a recurrence. Bennett Decl. at ¶35. As she explains, “numerous peer-reviewed scientific articles . . . show an association between PFAS exposure and brain tumors” and “my doctors think it is plausible that the PFAS I was exposed to . . . contributed to or caused my brain tumor.” *Id.* ¶ 39. These are risk factors that easily satisfy the criteria for demonstrating anticipated harm in this Court’s standing decisions. *See NRDC v. EPA*, 464 F.3d 1, 6-7 (D.C. Cir. 2006) (finding prospect of future injury sufficient to support standing based on a risk of non-fatal skin cancer of 1 in 200,000).

C. Any Remaining Factual Issues Regarding Plaintiffs’ Standing Should Be Resolved by Discovery Against Inhance in the District Court

The Inhance submissions to EPA contain comprehensive information about Inhance’s customers, their uses of fluorinated containers and the levels of PFAS in fluorinated products. However, Inhance has claimed the bulk of this information is protected from disclosure under TSCA section 14. Its withholding of critical use and exposure information from the public is being challenged by plaintiffs and EPA in litigation under the Freedom of Information Act. *PEER. v. EPA*, No. 24-0445

(D.D.C.).

While plaintiffs believe their declarations resolve any doubt about whether Mr. Fox and Dr. Bennett have been and remain exposed to PFAS from their use of fluorinated containers, any remaining uncertainty stems from Inhance's dogged opposition to releasing use and exposure information that would go far to resolve these issues. Thus, if the Court deems the current record inadequate to uphold plaintiffs' standing, it should direct the district court to allow plaintiffs to pursue discovery against Inhance. "[P]recisely because the plaintiff bears the burden of alleging facts demonstrating standing, we have encouraged district courts to 'give the plaintiff ample opportunity to secure and present evidence relevant to the existence of jurisdiction' where necessary." *Katz v. Donna Karan Company, LLC*, 872 F.3d 114, 121 (2d Cir. 2017) (citation omitted).

CONCLUSION

The decision of the lower court should be reversed and the case should be remanded for further proceedings consistent with the Court's opinion.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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